

Remarks/Arguments:

Rejections under 35 U.S.C. §103

Claims 16, 20-26 and 32 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,967,744 to Chua ("Chua") in view of U.S. Patent No. 5,890,490 to Aylsworth et al. ("Aylsworth") and U.S. Patent No. 4,249,527 to Ko et al. ("Ko"). Applicants respectfully traverse this rejection.

Independent claim 16 recites, *inter alia*, a system for delivering humidified gas to a patient. The system comprises a supply unit configured to deliver humidified gas and a delivery tube assembly having a delivery tube with a proximal end and a distal end. The delivery tube assembly also has a fitting positioned at the proximal end of the delivery tube and releasably coupled to said supply unit. The delivery tube assembly is configured to transfer heat to the humidified gas received from said supply unit. A nasal cannula is releasably coupled to the distal end of the delivery tube to receive humidified gas from the delivery tube of the delivery tube assembly. Emphasis added.

Independent claim 32 recites, *inter alia*, a method for delivering humidified gas to a patient. The method comprises the steps of releasably connecting a fitting of a proximal end of a delivery tube to a supply unit; releasably coupling a nasal cannula to a distal end of the delivery tube; and delivering humidified gas from the supply unit, through the delivery tube, and into the nasal cannula for delivery to the patient.

Chua discloses a breathing circuit that includes a patient connector 50 that is inserted into a patient's mouth for the patient to inhale the breathing gas generated by Chua's device. Co-axial tube 30 is used to provide an inspiratory supply line 40 that provides breathing gas from a ventilator 5 to a mouthpiece 54 and an expiratory tube 32 that allows expired air to be exhausted from the patient and to an exit connector 66 and back to the ventilator 5 through a return line 12. Additionally, Chua discloses only that the patient connector 50 is connected to a co-axial tube 30 by a swivel connection. Chua fails to disclose or suggest that the patient connector 50 is releasably connected to the tube 30. Further, Chua fails to disclose or suggest a nasal cannula that is releasably connected to the distal end of the delivery tube. Chua only discloses a mouthpiece that provides air to the patient's mouth (See, e.g., column 3, lines 11-12; Fig. 2).

Chua's operation requires the use of the expiratory tube 32. As the patient exhales, the patient "must exhale air out the expiratory tubing 32." Col. 4, lines 18-19. Emphasis added.

Aylsworth discloses a gas flow system that includes a nasal cannula 11 that is connected to an outlet port 9. Aylsworth also discloses that the nasal cannula 11 may include other patient connected devices, such as an oxygen mask. (See column 3, lines 61-65). Aylsworth also discloses a tube 31 that is coupled to a tee 29. (See column 4, lines 9-11). Aylsworth fails to disclose or suggest that the nasal cannula 11 is releasably connected to the outlet port 9 or that the tube 31 is releasably coupled to the tee 29.

Ko discloses a continuous positive airway pressure administration apparatus 20 that includes an adapter 144, a connector 146, and a nasal cannula 148. (See column 7, lines 65-66; Fig. 1). Ko fails to disclose or suggest whether the nasal cannula is releasably connected to the connector 146.

In the Office Action, it was acknowledged that the difference between Chua and claim 16 was a nasal cannula releasably coupled to the distal end of the delivery tube to receive humidified gas from the delivery tube of the delivery tube assembly. Nevertheless, the Office Action concluded that it would have been obvious to modify the respiratory mouthpiece or the like of Chua to substitute a mask and nasal cannula because it would have provided the advantages of ensuring a secure and covered patient connection via a mask and providing humidified gas directly to a patient's respiratory passages via a nasal cannula as taught by Aylsworth. It was further stated that, to the extent, if any, that the nasal cannula of Aylsworth may not be releasably coupled, resort is had to Ko, which is said to teach releasably coupling a nasal cannula or an endotracheal tube to a connector member of a gas delivery tube for the purpose of providing a means for releasably connecting a plurality of different patient interfaces to a gas delivery conduit. The Office Action further concluded that it would have been obvious to releasably couple a nasal cannula to the distal end of the gas supply tube of Chua because it would have provided a means for releasably connecting a plurality of different patient interfaces to a gas delivery conduit as taught by Ko.

Further, it was stated in the Office Action that claim 32 is substantially equivalent in scope to claim 16 and is included in Chua as modified by Aylsworth and Ko for the reasons set forth above with respect to claim 16.

Applicants base their traverse of this rejection on numerous grounds. Applicants respectfully submit that there is no suggestion to modify the references to arrive at the claimed invention. Also, Applicants submit that the proposed combination would be inoperative. Further, Applicants submit that the Office Action misinterprets at least the Ko reference and that Ko is insufficient to support the proposition set forth in the Office Action. Still further, Applicants respectfully submit that the Examiner has not provided any convincing reasoning why it would be obvious to combine the prior art as suggested. Finally, Applicants respectfully submit that, even if the cited prior art were to be combined as suggested by the Examiner, the combination would still fail to produce the claimed invention and therefore, does not provide a *prima facie* case of obviousness.

Unsuggested modification

In *Ex parte Metcalf*, 67 U.S.P.Q.2d 1633 (May 2, 2003), the U.S. PTO Board of Patent Appeals and Interferences stressed that there must be objective motivation to support an obviousness rejection. More specifically, the mere fact that teachings found in the prior art could be combined as proposed by an Examiner does not make the combination obvious "absent some teaching, suggestion or incentive supporting the combination." *Id.* at 1635 (citing *Carella v. Starlight Archery and Pro Line Co.*, 231 USPQ 644, 647 (Fed. Cir. 1986)). There is no suggestion in Chua to modify Chua to add a nasal cannula. Chua uses co-axial tube 30 to provide an inspiratory tube 40 and an expiratory tube 32 that are both connected to a patient connector 50 as part of a breathing circuit. As shown in Fig. 2, patient connector 50 is inserted in the patient's mouth. The expiratory tube 32 is critical to Chua's invention because it is used to transport expiratory gases away from the patient. Chua's breathing circuit requires an expiratory line to complete the circuit. The nasal cannula of the present invention is not suitable or intended for use in a breathing circuit because there is no return for expiratory gases. Also, nowhere does Chua suggest modifying his breathing device with any type of different end device to supply breathing gas to the patient. Further, nowhere does Chua suggest that the patient connector 50 is releasably connected to the co-axial tube 30. Therefore, Applicants respectfully submit that there is no suggestion in Chua to modify his invention to include the claimed nasal cannula that is releasably coupled to the delivery tube.

Further, none of the remaining cited art suggests substituting its preferred apparatus of delivering breathing gas with a nasal cannula. Ko suggests substituting an endotracheal tube for a nasal cannula (Col 10, lines 29-31). As for his nasal cannula, Ko only states that a nasal

cannula 148 is provided at a lower end of a vertical arm. See Col. 7, lines 66-67. As for his endotracheal tube, Ko teaches only to substitute the endotracheal tube (not shown) for the nasal cannula. Nowhere does Ko teach or suggest that either his cannula or endotracheal tube are releasably coupled to a delivery tube, as is recited in the present claims. Aylsworth discloses connecting his nasal cannula 11 to an outlet port 9. Aylsworth also suggests including an oxygen mask with his nasal cannula (Col. 3, lines 63-65). Aylsworth fails to disclose, however, how an oxygen mask is included with a nasal cannula. Additionally, Aylsworth also fails to disclose that either the nasal cannula or the oxygen mask are releasably coupled to the outlet port 9.

Further, neither Aylsworth nor Ko disclose or suggest using their devices as part of a breathing circuit, such as Chua's. Aylsworth and Ko each fail to disclose how to connect their respective end devices (Aylsworth's cannula/mask and Ko's cannula/endotracheal tube) to an expiratory line in a breathing circuit.

Inoperative combination

Chua discloses co-axial tube 30 to provide an inspiratory tube 40 and an expiratory tube 32 that are both connected to breathing connector 50 as part of a breathing circuit. Assuming, *arguendo*, that one were to attempt to substitute Chua's breathing connector 50 with a nasal cannula, there is no way to connect the nasal cannula so that expired gases pass from the nasal cannula through the expiratory tube 32. Therefore, Applicants respectfully submit that the suggestion to modify Chua with the nasal cannula and mask of Aylsworth, as suggested by the Examiner, would render Chua inoperative. Further, neither Chua nor Aylsworth disclose or suggest how any connection between a nasal cannula/mask combination would be made with the breathing connector 50. Therefore, even if the separate components *could* be combined as suggested in the Office Action, there is no support in either reference that teaches *how* such a combination would be physically made.

Misunderstood reference

In the Office Action, it was stated that Ko teaches a releasable coupling in col. 10, lines 29-31 (See page 3 of Office Action). Applicants respectfully submit that there is no disclosure or suggestion of releasably coupling nasal cannula anywhere in the disclosure. Contrary to the statement in the Office Action that Ko teaches releasably coupling a nasal cannula or an endotracheal tube to a connector member of a gas delivery tube, Applicants respectfully submit that Ko fails to disclose or suggest releasably coupling either the nasal cannula 148 or an

endotracheal tube to the connector member 146. Further, the figures fail to disclose that the nasal cannula is releasably connected to a delivery tube. Applicants respectfully submit that Ko should therefore be removed as a reference. Applicants respectfully submit that the remaining references, Chua and Aylsworth, fail to disclose or suggest a nasal cannula that is releasably coupled to the distal end of the delivery tube, as is recited in amended claim 16.

No convincing reasoning

In the Office Action, it is stated that “[i]t would have been obvious to releasably couple a nasal cannula to the distal end of the gas supply tube of Chua because it would have provided a means for releasably connecting a plurality of different patient interfaces to a gas delivery conduit as taught by Ko.” Office Action, page 3. Especially in view of the fact that Chua relates to a breathing circuit and that a nasal cannula would render the circuit inoperative, the Office Action has failed to present a convincing line of reasoning as to why the claimed subject matter as a whole, including its differences over the prior art, would have been obvious. In particular, the Office Action fails to state a reason as to why one would *want* to couple a nasal cannula to Chua’s supply line. Such modification would render the expiratory portion of Chua’s device inoperative, defeating the purpose of Chua’s invention.

Claimed features lacking

The Office Action suggested combining Chua, Aylsworth, and Ko to arrive at the invention recited in claim 16. Even if combined, however, the three references all fail to disclose or suggest a delivery tube releasably coupled to a supply unit or a nasal cannula releasably coupled to the delivery tube. The suggested combination, even if it were appropriate for sake of illustration, still fails to produce the claimed invention and therefore, does not provide a *prima facie* case of obviousness.

For at least the reasons cited above, Applicants respectfully submit that independent claims 16 and 32 are patentable over the cited prior art. Applicants respectfully request reconsideration and allowance of claims 16 and 32.

Claims 20-26 all depend, either directly or indirectly, from claim 16, and Applicants respectfully submit that claims 20-26 are patentable over the cited prior art for at least the same reasons as set forth above with respect to claim 16.

Claims 17, 18, and 27-30 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Chua in view of Aylsworth and Ko, and further in view of U.S. Patent No. 5,349,946 to McComb ("McComb"). Claims 17, 18, and 27-29 all depend, directly or indirectly, from amended claim 16, and Applicants respectfully submit that claims 17, 18, and 27-29 are patentable over the cited prior art for at least the same reasons as set forth above with respect to claim 16, and because the McComb reference does not overcome the deficiencies of the combination of Chua, Aylsworth, and Ko as set forth above. Applicants therefore respectfully request reconsideration and allowance of claims 17, 18, and 27-29.

Regarding independent claim 30, the Examiner stated that claim 30 is essentially equivalent in scope to claim 17. Chua, Aylsworth, and Ko are described above. McComb discloses a breathing device 10 in which a mouthpiece is inserted into the patient's mouth to administer breathing gas to the patient. See Fig. 1. McComb discloses a flow rate of between 2 and 150 liters per minute.

Applicants respectfully submit that, since so many references (4) had to be pieced together to attempt to arrive at the invention of claim 30, the Office Action is merely attempting to use hindsight reconstruction to "build" the invention from available parts, using Applicants' disclosure as a guide. Such piecing together of so many references indicates that the claim is *not* obvious.

Further, Applicants respectfully submit that the combination of Chua, Aylsworth, Ko, and McComb fails to teach or disclose the claimed method delivering humidified gas by coupling a nasal cannula to a delivery tube. The addition of McComb still does not address the deficiency of the other three references failing to disclose or suggest connecting a nasal cannula to Chua's supply line, as discussed above with respect to claim 16. Applicants therefore respectfully submit that the combination of Chua, Aylsworth, Ko, and McComb is improper and respectfully request reconsideration and allowance of claim 30.

Further, the Examiner rejected independent claims 31 and 33 under 35 U.S.C. 103(a) as being unpatentable over Chua in view of both McComb and Aylsworth. Regarding claim 31, the Examiner stated that the differences between Chua and claim 31 are the delivery of humidified gas at a flow rate of between about 1 and 8 liters per minute and a nasal cannula configured to be coupled to receive the humidified gas from the distal end of the delivery tube assembly. The

Examiner further states that McComb satisfies the flow rate teaching and that Aylsworth satisfies the teaching of connecting the nasal cannula to the delivery tube assembly.

Regarding claim 31, Applicants respectfully submit that there is no incentive to combine the references. Chua requires a breathing tube 50 that is inserted into the patient's mouth in order to provide the inhalation breathing gases and to expel the expiry gases. There is no incentive in Chua to substitute his mouth-inserted breathing tube 50 with a nasal cannula as recited in claim 31.

Further, as discussed above with respect to claim 16, Applicants respectfully submit that a combination of Chua with Aylsworth as suggested by the Examiner to achieve the method recited in claim 31 is improper. Chua discloses a co-axial breathing tube 30 that utilizes an inner tube 40 to provide breathing gas for inhalation by the patient and an external expiry tube 32 for taking expired gases away from the patient. Any suggestion to modify Chua with a nasal cannula of Aylsworth is improper, because such a combination would render Chua's invention unworkable. Exhaust gases exhaled by the patient would not get into Chua's expiry tube, rendering Chua unworkable for its intended purpose.

For at least these reasons, Applicants respectfully submit that the combination as suggested by the Examiner is improper, and request that the rejection of claim 31 be withdrawn.

Regarding claim 33, the Examiner stated that the claim is essentially equivalent in scope to claim 31. Applicants therefore repeat the arguments set forth above with respect to claim 31 and submit that, for at least these reasons, the combination as suggested by the Examiner is improper. Applicants therefore respectfully request that the rejection of claim 33 be withdrawn.

Conclusion

In light of the arguments set forth above, Applicants respectfully submit that claims 16-18 and 20-33 are in condition for allowance. Prompt reconsideration and allowance of same is respectfully requested.

Respectfully submitted,



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